UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	Judge Patti B. Saris Magistrate Judge Marianne B. Bowler

THE ROXANE DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR A FINDING OF SPOLIATION OF EVIDENCE AND FOR SANCTIONS

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While the Government inexplicably kept Ven-A-Care's complaint against Roxane sealed for nearly seven years, it simultaneously allowed critical evidence relevant to Roxane's defenses to be destroyed. As documented in the Abbott and Dey motions for spoliation of evidence and memoranda in support thereof, *see* Docket Nos. 6096-6097 and 6109-6110, respectively, which Roxane hereby joins, the Government failed to preserve large volumes of electronic and hard copy documents that are crucial to Roxane's ability to defend itself in this case. The arguments advanced by Abbott and Dey apply in equal force to this case.

Roxane has been particularly prejudiced by the Government's failure to preserve critical pricing data pertaining to the Medicare Durable Medical Equipment Carriers' (the "DMERCs") classification of Roxane drugs as generics or brands.[1] (*See* Ex. A at 12-24 (Roxane Defendants' Memorandum in Support of Their Motion for Summary Judgment (Docket No. 6200)); Ex. B at 53-79 (Corrected Roxane Local Rule 56.1 Statement of Facts (Docket No. 6207)) As explained in greater detail in Roxane's memorandum in support of its motion for summary judgment, the Government has advanced a damages model that depends on certain DMERCs' misclassification of Roxane's generic products as brands to improperly inflate damages by nearly *$1 billion*. (*See* Ex. A at 12-15; Ex. B at ¶¶ 225-44)

As a result, the underlying data and procedures that the DMERCs relied upon are undeniably of critical importance to Roxane's defenses. This data, however, has largely vanished or been destroyed due to the Government's failure to make any efforts to preserve it over the course of the nearly seven years this complaint remained sealed. Specifically, the

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[1] To avoid unnecessary repetition of arguments and evidence already before the Court, Roxane will cite to its memorandum in support of its motion for summary judgment and the accompanying statement of facts, which are attached as Exhibits A and B hereto, respectively.

Government made no efforts to preserve the electronic (and other) data on which the DMERCs purportedly relied in making their numerous classification errors.

In addition, the Government failed to ensure that State Medicaid programs preserved Medicaid claims data for each of the subject drugs during the entire period at issue. The actual State Medicaid claims data is critical to the issue of whether there is a "causal link between the defendant['s] actions" and the actual payment of a particular Medicaid claim. *See In re Pharm. Industry Avg. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 180-81 (D. Mass. 2007). Without the complete Medicaid claims data, Roxane cannot fully defend itself from the Government's lawsuit.

Accordingly, the Court should enter a finding of spoliation of evidence and preclude the Government from recovering any damages based on the DMERCs' misclassification of Roxane products as brands, rather than generics. The Court should also enter a finding of spoliation of evidence and preclude any recovery where the Medicaid claims data has been lost or destroyed.

LEGAL STANDARD

The Government, as a litigant, must preserve evidence when it "has notice that the evidence is relevant to litigation or when a party should have known that the evidence may be relevant to future litigation." *Zubulake v. UBS Warburg LLC*, 220 F.R.D. 212, 216 (S.D.N.Y. 2003); *United Med. Supply Co. v. United States*, 77 Fed. Cl. 257, 274 (2007) ("It is the duty of the United States, no less than any other party before this court, to ensure, through its agents, that documents relevant to a case are preserved."). Determining the scope of the duty to preserve "involves two related inquiries: when does the duty to preserve attach, and what evidence must be preserved?" *Zubulake*, 220 F.R.D. at 216. A party's duty to preserve attaches when litigation is "reasonably foreseeable." *Silvestri v. Gen. Motors Corp.*, 271 F.3d 583, 590-91 (4th Cir. 2001). And when a party fails to preserve evidence, this Court has the inherent power to impose

sanctions for spoliation, including awarding fees and costs. *United Med. Supply*, 77 Fed. Cl. at 264 n.7, 275-77; *Sacramona v. Bridgestone/Firestone, Inc.*, 106 F.3d 444, 446 (1st Cir. 1997) ("Under settled authority, the district court has inherent power to exclude evidence that has been improperly altered or damaged by a party where necessary to prevent the non-offending side from suffering unfair prejudice.").

I. THE GOVERNMENT FAILED TO PRESERVE IMPORTANT EVIDENCE RELATED TO DMERCS' MISCLASSIFICATIONS OF ROXANE'S GENERIC DRUGS.

A. The Government Failed To Preserve The Electronic Data Or Documents That DMERCs Relied Upon In Misclassifying Roxane's Drugs As Brands, Rather Than Generics.

Roxane has been severely prejudiced by the Government's failure to preserve electronic pricing data and related documents that certain DMERCs relied upon to misclassify generic ipratropium bromide drugs as brands. As described more fully in Roxane's memorandum in support of its motion for summary judgment, the Government relies upon the DMERCs' misclassification of the Novaplus-label ipratropium bromide generic product[2] as a brand to artificially inflate damages by nearly $1 billion.[3] (*See* Ex. A at 12-23; Ex. B at ¶ 228-43) Thus, the data that the DMERCs purportedly relied upon to implement their internal procedures for

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[2] The Novaplus-label ipratropium bromide product was a generic drug identical to the Roxane-label ipratropium bromide product. It was sold exclusively to the Novation GPO's hospital members under the Novaplus, rather than the Roxane, label. *See generally* Ex. B. at ¶¶ 135-50.

[3] Although the misclassification of Novaplus as a brand had no impact upon Medicare payments in the real world (because the Novaplus and Roxane-label AWPs were identical at all times), the Government's recreation of a "but for" world under the Novaplus Model creates a massive hypothetical impact. (*See* Ex. B at ¶¶ 237-42) Specifically, the Government replaces the actual Novaplus AWPs with "revised AWPs" based on sales transactional data. (*See id.* at ¶ 229) Because the regulations allowed payments to be based on "the lowest brand AWP," in the Government's "but-for" world the DMERCs' misclassification of Novaplus as a "brand" allows the Government to convert the "revised Novaplus AWP" into the new "lowest brand AWP." (*See id.* at ¶¶ 240-42) As a result, these "revised Novaplus AWPs" now become the hypothetical payment bases for *all* quarters and *all* ipratropium bromide claims, even though it is unlikely that *any* Novaplus products were ever reimbursed under Medicare Part B. (*Id.*)

classifying drugs as either generics or brands has massive implications in this case.[4] Accordingly, the Government should have made efforts to preserve this data and all related documents. As shown below, this certainly did not occur.

During the pertinent time period when the Novaplus-label products appeared in the DMERC pricing arrays (approximately 2001 through 2004), the DMERCs appear to have relied extensively on an electronic database provided by the Redbook pricing compendia on quarterly CD-roms (the "Redbook CDs" or the "Redbook Database"). (*See* Ex. C, 8/26/08 Eiler Dep. 133-36; Ex. D, 3/13/08 Helton Dep. 44-45, 147; Ex. E, 2/28/08 Stone Dep. 113; Ex. F, 2/29/08 Stone Dep. 284-85) Moreover, at least some of the DMERCs relied on information contained on the Redbook CDs to determine whether the Roxane- and Novaplus-label ipratropium bromide drugs should be classified as generics or brands. (Ex. G, 9/23/08 Eiler Dep. 600-03; Ex. H, Roxane Ex. 118 at AWP033-0434-35, AWP033-372-73, AWP033-268-69, AWP033-1128-29, AWP033-987-88 (Adminastar pricing arrays referring to "Redbook Database" as the source of pricing information and categorizing Novaplus-label ipratropium bromide in the brand arrays)) Specifically, some of the DMERCs reviewed the Redbook CDs to determine whether a drug name was represented in capital or lower case letters in the database, which, according to the DMERCs' internal criteria, supposedly identified which products were "generally" brands. (Ex. C, 8/26/08 Eiler Dep. 145-46; Ex. G, 9/23/08 Eiler Dep. 485, 547-49, 600-03)

The data on the quarterly Redbook CDs did not last indefinitely. Instead, each quarterly update erased all the data on the prior quarter's Redbook CD:

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[4] As discussed in Roxane's memorandum in support of its motion for summary judgment, the DMERCs' internal procedures were inconsistent with regulatory mandates, and, moreover, the DMERCs failed to implement even their own idiosyncratic methodology in a consistent fashion. (*See* Ex. A at 12-23; Ex. B at ¶ 228-43) Although these factors independently negate causation here, they do not otherwise lessen or obviate the Government's obligation to preserve pertinent data and documents.

Q: Now, it's my understanding that these [Redbook] CDs cease to be usable after a certain period of time.

A: They're not valid – when you put a new CD in the next quarter, then you cannot go back and access the previous.

* * *

Q: And that [Redbook] CD, when you loaded it, would delete the date provided by the previous CD, is that right?

A: Correct.

Q: And there was no way to keep a record of what the previous data was?

A: Other than doing a hard copy print.

(Ex. I, 8/27/08 Eiler Dep. at 294-95) As a result, the data on all the Redbook CDs from 2001 through 2004, which appears to be the pertinent time period when the Novaplus-label product was identified in the Redbook CDs, was erased and cannot be retrieved from the Redbook CDs. (*Id.*)

The Government has not produced ***any*** of these Redbook CDs, nor has it attempted to restore any of this data. Instead, the Government's entire production of data with respect to the Redbook CDs is limited to a handful of hard copy printouts of selective pages from the CDs. (*See, e.g.,* Ex. J, April 2000 Redbook CD Printout) And it appears that the few scattershot pages produced with respect to the Novaplus-label ipratropium bromide products were simply whatever pages the DMERCs happened to maintain in their files, rather than the fruit of any systematic litigation hold. Moreover, the few pages produced by the Government do not contain the distinction between capital and lower case letters that the DMERCs apparently looked to in classifying generic versus brands – those pages were contained in a different section of the

Redbook database (located on the CDs), which the Government has also failed to produce. (Ex. G, 9/23/08 Eiler Dep. 597-603)[5]

In short, there is no way for Roxane to review whether the DMERCs interpreted the listings on the Redbook CDs in a manner consistent with their own internal classification criteria. As discussed below, all evidence indicates that the DMERCs did *not* properly review the data on the Redbook CDs.

B. Roxane Has Been Prejudiced By The Government's Inexplicable Failure To Maintain Electronic Data Essential To Its Damages Claims.

Roxane has suffered prejudice from the Government's inexplicable failure to maintain and preserve the materials that the DMERCs used to misclassify the Novaplus-label products as brands. As discussed in Roxane's memorandum in support of its motion for summary judgment, the Government is precluded from obtaining recovery for any damages that rely on the DMERCs' errors because the DMERCs improperly ignored regulatory mandates on how to classify drugs as brands or generics, and instead adopted their own idiosyncratic classification methodologies. (*See* Ex. A at 16-20) Setting aside these fundamental errors, Roxane nonetheless is unable to re-create precisely what some of the DMERCs did pursuant to their own internal procedures because that evidence no longer exists. For instance, Roxane's review of the hard copy Annual Redbook publishing compendia, which presumably contained identical information pertaining to the Novaplus-label products as the Redbook CDs, demonstrates that under the DMERCs' own idiosyncratic procedures there was ***no*** basis to classify these products as brands,

[5] The Government cannot claim that its burden to preserve this evidence was onerous. To the contrary, only four DMERCs processed ipratropium bromide claims during the pertinent time period, and they all relied on the same publishing compendia (Redbook). (*See* Ex. B. at ¶ 163) Moreover, because the Redbook CDs were updated only quarterly, the total number of CDs to preserve per DMERC was likely no greater than ten or twelve CDs in total.

rather than generics. (*See id.* at 19-20) Roxane believes that the Redbook CDs would similarly demonstrate that the DMERCs' misclassification of the Novaplus-label ipratropium bromide not only deviated from regulatory requirements, but also violated the DMERCs' own internal procedures. (*See id.*) As a result, Roxane has been prejudiced because the destruction of this evidence prevented Roxane from cross-examining the DMERC witnesses on these materials or otherwise further bolstering its defenses with this evidence.

The Government cannot credibly claim that it was unaware of its duty to preserve this evidence. As an initial matter, before Ven-A-Care filed its complaint against Roxane in April 2000, lawsuits against Abbott and Dey (and other manufacturers) pertaining to Medicare claims processed by DMERCs had been pending before the Department of Justice for *years*. And, as documented in Abbott's memorandum in support of its motion for spoliation, the Government did *nothing* during those years (or subsequent years) to preserve relevant evidence. In any event, as of April 2000, the Government was on notice of its duty to preserve pertinent electronic and hard copy documents pertaining to ipratropium bromide, but, again, did nothing to preserve the crucial underlying data used by the DMERCs. Indeed, the Novaplus-label NDCs did not appear in the DMERC arrays until 2001, and thus the Government had at least a year *after* the filing of the complaint to begin preserving this evidence. It did nothing of the sort.

II. THE GOVERNMENT ALSO FAILED TO PRESERVE STATE MEDICAID CLAIMS DATA.

The Government's failure to preserve State Medicaid claims data has likewise greatly prejudiced Roxane. This Court has repeatedly held that that there must be a "causal link" between the defendant's actions and the actual payment of a Medicaid claim. *See e.g.*, *In re Pharm. Industry Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 180. The law thus requires a claim-by-claim inquiry into how a particular Medicaid claim was paid – an inquiry that

necessitates an analysis of actual State Medicaid claim data. *See id.* But, as demonstrated in the Abbott motion for spoliation and sanctions, the Government's failure to preserve evidence has resulted in the destruction of State Medicaid claims data from numerous States. (*See* Docket No. 6097, at 1-2, 14; *see also* Ex. B, at ¶¶ 260-62, 287-90)

In the Roxane case, the Government has only produced State Medicaid claims data from thirty-one Medicaid programs, and even where it has produced such data, it has failed to produce complete data from all pertinent quarters for all but one of the States at issue. (*See* Ex. B, at ¶¶ 260-62, 287-90) Moreover, the Government failed to produced any State Medicaid claims data from eighteen different State Medicaid programs. (*See* Ex. B, at ¶ 262) The Government compounds its violation of discovery requirements by relying for its liability and damages analyses on other data sources that do not reveal how any particular Medicaid claim was paid and thus cannot speak to the issue of whether Roxane's AWPs and WACs caused the actual payment of the claim. (*See* Ex. B, at ¶¶ 260-62, 287-90) It is the actual State Medicaid claims data, however, that is critical to the predicate inquiry of whether the Medicaid claims at issue here were paid based on the allegedly false AWPs or WACs. *In re Pharm. Industry Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 180-81. Without this critical evidence, the Government has deprived Roxane of the data necessary to defend itself against the allegations made in this lawsuit.

III. SANCTIONS ARE APPROPRIATE AGAINST THE GOVERNMENT.

In short, while the Government inexplicably kept Ven-A-Care's complaint sealed for nearly seven years, it simultaneously allowed significant evidence relevant to Roxane's defenses here to be destroyed. Under these circumstances, sanctions are warranted. *See Sacramona*, 106 F.3d at 446; *Blinzler v. Marriott Intern., Inc.*, 81 F.3d 1148, 1159 (1st Cir. 1996); *Silvestri*, 271 F.3d at 594; *United Med. Supply*, 77 Fed. Cl. at 264 n.7, 275-77. Specifically, Roxane

respectfully requests a ruling from the Court that (1) the Government has spoliated evidence; (2) the Government be precluded from recovery of any damages that rely on the DMERCs' misclassification of Novaplus-label ipratropium bromide products as brands; and (3) the Government be precluded from recovery in the eighteen States in which it has failed to produced State Medicaid claims data (*see* Ex. B., at ¶ 262) or in any quarter for the other thirty-one Medicaid programs in which it has also failed to produce the actual State Medicaid claims data (*see* Ex. B, at ¶¶ 262, 287-90). Finally, Roxane respectfully requests that the Court award fees and costs against the Government, as well as any other appropriate sanction or relief, for the Government's spoliation of evidence.

CONCLUSION

For all the foregoing reasons, the Court should find that the Government has spoliated relevant evidence in this case and impose the appropriate sanctions, as described above.

Dated: July 9, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on July 9, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale
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